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| Applicant's or agent's file reference WNMROGM.5.PCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416) | |
| International application No. PCT/GB 03/03788 | International filing date (day/month/year) 28.08.2003 | Priority date (day/month/year) 28.08.2002 |
| International Patent Classification (IPC) or both national classification and IPC A61F5/455 | | |
| Applicant OWEN GREENINGS & MUMFORD LIMITED et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☒ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

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|---|---|
| Date of submission of the demand 29.03.2004 | Date of completion of this report 13.12.2004 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Lickel, A Telephone No. +49 89 2399-6068 |



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/03788**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-28 as originally filed

Claims, Numbers

1-17 received on 24.11.2004 with letter of 22.11.2004

Drawings, Sheets

1/10-10/10 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 4

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

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☐ complied with.

☒ not complied with for the following reasons:

see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-3,5-17 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|----------|
| Novelty (N) | Yes: Claims | 1-3,5-16 |
| | No: Claims | 17 |
| Inventive step (IS) | Yes: Claims | 1-3,5-16 |
| | No: Claims | 17 |
| Industrial applicability (IA) | Yes: Claims | 1-3,5-17 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

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EXAMINATION REPORT - SEPARATE SHEET**

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Re Item III

1. Claim 4 refers to an angle of the notional contact plane with respect to the horizontal when the user is reclined or supine. Since this angle clearly depends on the use of the device and is not a device-specific feature, this claim is not clear and thus no examination will be carried out for claim 4.

Re Item IV

Lack of unity of invention

2. The present application lacks unity in the sense of Rule 13.1 PCT, as it comprises two inventions, as claimed in independent claims 1 and 17, without having a general inventive concept linking the two inventions.

The common technical concept is known in the state of the art, see for example US-A-5 002 541 (D1) or EP-A-0 185 517 (D2), each of them disclosing:

A urine collection device (D1: 10; D2: fig. 1), suitable for attachment to a pump and suitable for a user in a supine or reclined position, said device including:

an open-mouthed container (D1: 138; D2: fig. 2) having a rim around the mouth for being urged in use to seat generally around the periphery of the urine discharge region to receive urine discharged from the urethra,
the container being adapted to fit between the legs of a user in a supine or reclined position,
the container having at its lower part a reservoir basin (D1: col. 7, line 35; D2: col. 3, line 51) in which fluid may collect in use when the container is applied to a user in a supine or reclined position, and
an outlet in the lower part of the reservoir basin (D1: 184; D2: 6) through which urine may be drawn from the container.

Notwithstanding this lack of clarity, claims 1-3 and 5-17 will be examined.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or

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industrial applicability; citations and explanations supporting such statement

3. Reference is made to the following document:

D1: US-A-5 002 541 (CONKLING J MICHAEL ET AL) 26 March 1991 (1991-03-26)
D2: EP-A-0 185 517 (THOMAS STEPHEN JOHN ;THOMAS MADELINE (GB)) 25
June 1986 (1986-06-25)

4. The document D1 is regarded as being the closest prior art and shows all the features of the preamble of claim 1.

The subject-matter of claim 1 differs from this known urine collection device in that it comprises a rim having a perineal wall portion to engage edgewise with the perineum, and in that the container is provided with a vent to allow venting of air through a wall of the container.

While the edgewise engagement provide a particularly good fluid-tight seal, the venting prevents a harmful build-up of negative pressure in the container when the urine is withdrawn from the container by means of a pump.

D2 discloses a venting mechanism, however it is directed towards allowing air escape from the urine collecting vessel and not for exchange of air through a wall of the container.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

- 4.1 Claims 2, 3 and 5-16 are dependent on claim 1 and meet the requirements of the PCT with respect to novelty and inventive step.
5. The subject-matter of claim 17 does not fulfill the requirements of Article 33(2) PCT for lack of novelty.

The features of the characterising part have been disclosed in D1, see in particular fig. 15, where the part of the collecting cup (175) which is closest to the mouth of the container (i.e. right lower part of fig. 15) is at an angle, with respect to the plane

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defined by the upper and lower ends of the rim, which falls within the range given in claim 17.

6. The industrial applicability of claims 1-3 and 5-17 is self-explicatory.
7. Claim 6 incorrectly refers to claim 6 rather than claim 5.
8. Documents D1 and D2 are not identified in the description (Rule 5.1(a)ii PCT).